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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Kamm et al.

Examiner:

Mathew, F. C.

Serial No.:

09/815,528

Group Art Unit:

3764

Filed:

March 23, 2001

For:

METHOD AND APPARATUS FOR STIMULATING ANGIOGENESIS AND

WOUND HEALING BY USE OF EXTERNAL COMPRESSION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Declaration under 37 C.F.R. § 1.131

I, Roger D. Kamm, declare as follows:

- I am currently a Professor in the Department of Mechanical Engineering and the 1. Biological Engineering Division at the Massachusetts Institute of Technology, Cambridge, Massachusetts. My research focuses on biomedical fluid dynamics, computational fluid dynamics, cell mechanics, and biomedical engineering. A copy of my curriculum vitae is attached as Exhibit A.
- I am a co-inventor of the subject matter disclosed and claimed in United States Patent 2. Application Serial Number 09/815,528, filed March 23, 2001, and entitled "Method and Apparatus for Stimulating Angiogenesis and Wound Healing by Use of External Compression" (the '528 application).
- This declaration is presented for the purpose of removing from consideration by the 3. Examiner the reference by Lewis (U.S. Patent 6,620, 116 (the '116 patent), filed December 8, 2000, and issued September 16, 2003).
- 4. On a date before December 8, 2000, the filing date of the '116 patent, Dr. Jonathan Gertler and I conceived of a system for stimulating angiogenesis and promoting wound healing by using external graded sequential compression to induce a change in the shear stress on the

endothelial cells of a patient's vasculature. The endothelial cells experiencing a change in shear stress secrete factors which stimulate angiogenesis and/or promote wound healing.

- 5. Exhibit B is the completed MIT Technology Disclosure form submitted by myself and Dr. Gertler to the MIT Technology Licensing Office describing the invention in the '528 application. Attached to the disclosure form is a manuscript entitled "Numerical Simulation of Enhance External Counterpulsation. Part II: Hemodynamic Results," which describes a computational model of the inventive system. The first page of the disclosure form bears a date prior to December 8, 2000; however, this date has been redacted.
- 6. I declare that all statements made herein of my own knowledge are true, and that those statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like are made punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the '528 application or any patents that may issue thereon.

Roger D. Kamm, Ph.D.

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